STATE OF RHODE ISLAND
EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES
5/21/2015 PUBLIC NOTICE OF PROPOSED CATEGORY II CHANGE TO RHODE ISLAND'S COMPREHENSIVE 1115 WAIVER DEMONSTRATION

In accordance Rhode Island General Laws 42-35, notice is hereby given that the Executive Office of Health and Human Services (EOHHS) will seek federal authority to implement the following Category II Change to Rhode Island's Comprehensive 1115 Waiver Demonstration (project no. 11-W-00242/1):

Cortical Integrative Therapy

Cortical Integrative Therapy (CIT) is a non-invasive diagnostic and treatment program for brain-based disorders. CIT is an innovative approach for detecting and stabilizing abnormal structural and functional brain lesions resulting from acquired brain injury or developmental disabilities, as well identifying the competent stimulus to be an effective treatment for the patient. Specifically, CIT uses objective measures of subtle functional changes across a wide range of domains—sensory systems including pupillary responses, motor systems, the autonomic system and the vestibular system—to diagnose a brain dysfunction. In addition, CIT uses a algorithm-based approach to analyze these data to identify the laterality and longitudinal level of a neurological lesion. CIT algorithms determine how best to stabilize the basic underlying systems of homeostasis so that the patient can benefit from treatment. Finally, CIT delivers a detailed treatment plan including the type, duration, and frequency of noninvasive treatment modalities to enable the patient to quickly recover optimal functionality.

This approach of precise diagnosis and active treatment is a profound departure from present day management practices for acquired brain injury and dysfunction which typically entails passive rest and intermittent monitoring. Rather than managing symptoms, CIT identifies and treats the underlying neurophysiological dysfunction or injury.

This development leads to improved brain function without requiring medication or surgery. The therapy is effective in enhancing level of function, cost effective and may result in beneficial cost avoidance for patients who may not require additional costly therapies due to increased functioning.

EOHHS will seek federal authority to launch a 100-patient per year pilot for this treatment. The program will be a population-based, fully capitated pilot. This effort will be guided and evaluated by the twin goals of improving patient health while lowering cost to the healthcare system.

This proposed Category II change is accessible on the EOHHS website (www.eohhs.ri.gov) or available in hard copy upon request (401-462-1965 or RI Relay, dial 711). Interested persons should submit data, views, or written comments by June 21, 2015 to Darren J. McDonald, Office of Policy and Innovation, Executive Office of Health

and Human Services, 57 Howard Avenue, Cranston, RI, 02920, or darren.mcdonald@ohhs.ri.gov.

In accordance with the Rhode Island General Laws 42-35-3, a hearing will be conducted to receive public testimony on the proposed Category II change if requested by twenty-five (25) persons, or by an agency or association having at least twenty-five (25) members. A request for a hearing must be made within thirty (30) days of this notice.

The Executive Office of Health and Human Services does not discriminate against individuals based on race, color, national origin, sex, gender identity or expression, sexual orientation, religious belief, political belief, or disability in acceptance for or provision of services or employment in its programs or activities.

Rhode Island Comprehensive Section 1115 Demonstration
Project Number: 11-W-00242/1

Category II Change
Change Name: Cortical Integrative Therapy
Change Number: 15-01-CII

Date of Request:	June 22, 2015
Proposed Implementation Date: *(45 day notice required)*	August 6, 2015

Fiscal Impact

	FFY 2015	FFY 2016	FFY 2017	FFY 2018
State:	$84,000	$500,000	$500,000	$416,000
Federal:	$84,000	$500,000	$500,000	$416,000
Total	$168,000	$1,000,000	$1,000,000	$832,000

Description of Change:
Attachment A

Assurances:
Attachment B

Standard Funding Questions:
Attachment C

Attachment A: Description of Change

Summary:

The Rhode Island Executive Office of Health and Human Services (EOHHS) is submitting this change request to the Rhode Island Comprehensive Section 1115 Demonstration to launch a 3-year pilot program to evaluate the clinical and fiscal effectiveness of Cortical Integrative Therapy (CIT). EOHHS requests an effective date of August 6, 2015, to launch this program. The first year of the pilot will thus run from August 2015 to July 2016 with the second year extending from August 2016 to July 2017, and the third year of the pilot running from August 2017 through July 2018.

State statutory authority for this change request was obtained in 2013:

"(i) Cortical Integrative Therapy. The Medicaid single state agency shall seek to create a new service entitled Cortical Integrative Therapy.

Cortical Integrative Therapy (CIT) is a non-invasive diagnostic and treatment program for brain-based disorders. CIT is an innovative approach for detecting and stabilizing abnormal structural and functional brain lesions resulting from acquired brain injury or developmental disabilities, as well identifying the competent stimulus to be an effective treatment for the patient. Specifically, CIT uses objective measures of subtle functional changes across a wide range of domains—sensory systems including pupillary responses, motor systems, the autonomic system and the vestibular system—to diagnose a brain dysfunction. In addition, CIT uses an algorithm-based approach to analyze these data to identify the laterality and longitudinal level of a neurological lesion. CIT algorithms determine how best to stabilize the basic underlying systems of homeostasis so that the patient can benefit from treatment. Finally, CIT delivers a detailed treatment plan including the type, duration, and frequency of noninvasive treatment modalities to enable the patient to quickly recover optimal functionality.

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This development leads to improved brain function without requiring medication or surgery. The therapy is effective in enhancing level of function, cost effective and may result in beneficial cost avoidance for patients who may not require additional costly therapies due to increased functioning.

Creating this new service may require Category II changes under the terms and conditions of the Global Consumer Choice Waiver and the adoption of new or amended rules, regulations, and procedures;"

2013 H5127 Sub A As Amended - RELATING TO MAKING APPROPRIATIONS FOR THE SUPPORT OF THE STATE FOR THE FISCAL YEAR ENDING JUNE 30, 2014", Section 6, page 13, lines 20-25.

Rhode Island Medicaid is requesting this approval under the existing 1115 authority for a waiver of Comparability of Eligibility Standards.[1] This request conforms to the Rhode Island Medicaid Reform Act of 2008 which directed the state's Medicaid program to establish a "sustainable cost-effective, person-centered, and opportunity driven program utilizing competitive and value-based purchasing to maximize available service options" and "a results-oriented system of coordinated care."[2] The RI Medicaid Reform Act guided the development and implementation of Rhode Island's initial Global Consumer Choice Compact Section 1115 Demonstration, the precursor to the state's current 1115 waiver.

This change request is submitted as a Category II submission.

Background:

Cortical Integrative Therapy (CIT) is a non-invasive diagnostic and treatment program for brain-based disorders. Cortical Integrative Therapy (CIT) is a non-invasive diagnostic and treatment program for brain-based disorders. CIT is an innovative approach for detecting and stabilizing abnormal structural and functional brain lesions resulting from acquired brain injury or developmental disabilities, as well identifying the competent stimulus to be an effective treatment for the patient. Specifically, CIT uses objective measures of subtle functional changes across a wide range of domains—sensory systems including pupillary responses, motor systems, the autonomic system and the vestibular system—to diagnose a brain dysfunction. In addition, CIT uses an algorithm-based approach to analyze these data to identify the laterality and longitudinal level of a neurological lesion. CIT algorithms determine how best to stabilize the basic underlying systems of homeostasis so that the patient can benefit from treatment. Finally, CIT delivers a detailed treatment plan including the type, duration, and frequency of noninvasive treatment modalities to enable the patient to quickly recover optimal functionality.

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[1] Section 1902(a)(17) of the Social Security Act.
[2] Rhode Island General Law section 42-12.4.

EOHHS believes this therapy is effective in enhancing the level of function for patients with brain-based disorders. As such, CIT holds the potential to be cost effective and may result in beneficial cost avoidance for patients who, due to increased brain function attributable to the non-invasive and non-pharmaceutical Cortical Integrative Therapy, may not require additional costly therapies, including surgeries, extended costly therapies and long-term pharmaceutical therapy.

To fully evaluate the clinical and financial effectiveness of CIT, EOHHS will launch a 3-year evaluation with up to 100 patients enrolled in each year of the pilot program. The 3-year time frame will allow for patient recruitment, treatment, and enable the state to conduct quality evaluation along a 36-month continuum. A patient sample of up to 100 beneficiaries per year will minimize the logistical and administrative burdens of initiating the program and will facilitate rapid, detailed analysis of patient outcomes by EOHHS. Furthermore, the relatively small annual size of the patient pool will enable the state to conduct a detailed analysis of the costs and costs avoided through the pilot treatment modality.

Patients Eligible to Enroll in the Pilot Program:

Only Medicaid-eligible individuals with the following diagnoses will be able to request enrollment in the CIT pilot:

Diagnosis:	Description:
337	Idiopathic peripheral autonomic neuropathy
345	Epilepsy and recurrent seizures
348	Other conditions of the brain
351	Facial nerve disorders
352	Disorders of other cranial nerves
781	Abnormal involuntary movement
781.1	Disturbance of sensation of smell and taste
781.2	Abnormality of gait
781.3	Lack of coordination
781.8	Neurologic neglect syndrome
784.1	Throat pain
784.3	Aphasia
784.4	Aphasia
784.5	Other speech disturbance
784.49	Other voice disturbance

A request for CIT will be reviewed by Rhode Island Medicaid to confirm that an eligible diagnosis is present.

Services Included in CIT Pilot:

Beneficiaries participating in the CIT pilot will receive services in the following areas:

Evaluation and management
Chiropractic manipulation
Video Nystagmography—Oculomotor testing

The Pilot is capitated for the population of patients enrolled on an annual basis and utilizes a bundled payment for each patient in order to better facilitate the demonstration of potential cost avoidance in the independent evaluation. RI EOHHS intends to demonstrate both improved function for the patients enrolled and cost effectiveness for this bundled payment that will provide access to this effective, non-invasive and non pharmaceutical treatment modality.

The specific codes associated with each service are identified below:

Evaluation and Management:

New Patient
99201 Self-limited/Minor evaluation
99202 Low to Moderate evaluation
99203 Moderate evaluation
99204 Moderate to High evaluation
99205 Moderate to High evaluation

Established Patient
99212 Self-limited/Minor evaluation
99213 Low to moderate evaluation
99214 Moderate to high evaluation
99215 Moderate to high evaluation

Chiropractic Manipulation:

CMT—manual treatment to influence joint and neurophysiological function.
The 5 spinal regions are cervical, thoracic, lumbar, sacral, and pelvic.
The 5 extra-spinal regions are head, lower extremities, upper extremities, rib cage, and abdomen.

98940 CMT: Spinal (1-2 regions)
98941 CMT: Spinal (3-4 regions)
98942 CMT: Spinal (5 regions)
98943 CMT: Extraspinal (1 or more regions)

Physical Medicine and Rehabilitation
97001 Physical therapy evaluation
97002 Physical therapy re-evaluation
97003 Occupational therapy re-evaluation
97004 Occupational therapy re-evaluation

Supervised Modalities
97010 Hot or cold packs
97012 Tractions, mechanical
97014 Electrical stimulation

Constant Attendance
97032 Electrical stimulation
97033 Electrical current therapy
97034 Contrast bath therapy
97035 Ultrasound therapy
97036 Contrast bath therapy
97039 Physical therapy treatment

Therapeutic Procedures
97110 Therapeutic exercises
97112 MM
97116 Gait training therapy
97139 Physical medicine procedure
97150 Group therapeutic procedures
97140 Myofascial release
97140 Manual traction
97124 Massage therapy
97530 Therapeutic activities
97532 Cognitive skills development
97533 Sensory Integration
97535 Self-care management training

Tests and measurements
97750 Physical performance test

Video Nystagmography:

Vestibular Function Tests
92541 Spontaneous nystagmus test
92542 Positional nystagmus test
92543 Caloric vestibular tests
92544 Optokinetic nystagmus test
92545 Oscillating tracking test
92546 Sinusoidal rotational test
92547 Electrical

Special Ophthalmological Services
92081 Blind spot map

Evaluation Plan:

Upon CMS's approval of the Cortical Integrative Therapy pilot, EOHHS will contract with an independent evaluator to develop the clinical and financial evaluation measures for this program. Those measures will be incorporated into an overall evaluation strategy and will serve as the basis for the cumulative CIT evaluation report which will be produced at the conclusion of the 3-year period.

EOHHS will submit these evaluation measures to CMS for review during the year one implementation of the pilot.

This evaluation plan will articulate quantifiable measures in the following areas:

1. Patient Outcomes
2. Financial Measures

Patient outcomes will be defined when the evaluation plan is promulgated. As patients are enrolled in the pilot, they will be screened in accordance with these measures to establish a treatment baseline. EOHHS will oversee chart audits and medical reviews at 12-month intervals after the CIT program launches. In addition, patient outcomes will be compared to those of the patients randomly selected for the financial control group described below. This comparison will also be based on chart audits and medical reviews.

Financial evaluation measures will be recorded semi-annually. At the beginning of each pilot year, EOHHS will randomly select 100 beneficiaries with similar diagnoses and functional limitations to the patients enrolled in CIT. Those 100 non-CIT enrolled patients will serve as a financial control group for the study. EOHHS will then track the costs associated with the control group alongside those of the CIT beneficiaries to register cost-avoidance trends associated with this new treatment.

These semi-annual reports will serve as the basis for the overall CIT evaluation that EOHHS will finalize at the conclusion of the 3-year period.

Attachment B: Assurances

The State assures the following:

- This change is consistent with the protections to health and welfare as appropriate to title XIX of the Social Security Act (the Act).
- The change results in appropriate efficient and effective operation of the program, including justification and response to Funding Questions.
- This change would be permissible as a State Plan or Section 1915 Waiver Amendment and is otherwise consistent with sections 1902, 1903, 1905, and 1906, Current Federal Regulations, and CMS Policy.

Attachment C: Standard Funding Questions

1. Section 1903(a)(I) provides that Federal matching funds are only available for expenditures made by States for services under the approved State plan. Do providers receive and retain the total Medicaid expenditures claimed by the State (includes normal per diem, supplemental, enhanced payments, other) or is any portion of the payments returned to the State, local governmental entity, or any other intermediary organization? If providers are required to return any portion of payments, please provide a full description of the repayment process. Include in your response a full description of the methodology for the return of any of the payments, a complete listing of providers that return a portion of their payments, the amount or percentage of payments that are returned and the disposition and use of the funds once they are returned to the State (i.e., general fund, medical services account, etc.)

   Providers keep all of the Medicaid payments made by the state.

2. Section 1902(a)(2) provides that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the state share of each type of Medicaid payment (normal per diem, supplemental, enhanced, other) is funded. Please describe whether the state share is from appropriations from the legislature to the Medicaid agency, through intergovernmental transfer agreements (IGTs), certified public expenditures (CPEs), provider taxes, or any other mechanism used by the state to provide state share. Note that, if the appropriation were not to the Medicaid agency, the source of the state share would necessarily be derived through either through an I GT or CPE. In this case, please identify the agency to which the funds are appropriated. Please provide an estimate of total expenditure and State share amounts for each type of Medicaid payment. If any of the nonfederal share is being provided using IGTs or CPEs, please fully describe the matching arrangement including when the state agency receives the transferred amounts from the local governmental entity transferring the funds. If CPEs are used, please describe the methodology used by the state to verify that the total expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b). For any payment funded by CPEs or IGTs, please provide the following:
   (i) a complete list of the names of entities transferring or certifying funds;
   (ii) the operational nature of the entity (state, county, city, other);
   (iii) the total amounts transferred or certified by each entity;
   (iv) clarify whether the certifying or transferring entity has general taxing authority: and,
   (v) whether the certifying or transferring entity received appropriations (identify level of appropriations)

   The state's share of the payments comes from annual legislative appropriations to the designated Medicaid Single State agency.

3. Section 1902(a)(30) requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a)(1) provides for Federal financial participation to States for expenditures for services under an approved State plan. If supplemental or enhanced payments are made, please provide the total amount for each type of supplemental or enhanced payment made to each provider type.

   The state will not be making enhanced or supplemental payments for this pilot.

4. For clinic or outpatient hospital services please provide a detailed description of the methodology used by the state to estimate the upper payment limit (UPL) for each class of providers (State owned or operated, non-state government owned or operated, and privately owned or operated). Please provide a current (i.e., applicable to the current rate year) UPL demonstration.

   Not applicable

5. Does any governmental provider receive payments that in the aggregate (normal per diem, supplemental, enhanced, other) exceed their reasonable costs of providing services? If payments exceed the cost of services, do you recoup the excess and return the Federal share of the excess to CMS on the quarterly expenditure report?

   Payments do not exceed the cost of services. If, in some instance, payment did exceed the cost of service, the state would recoup that money and return the federal share to CMS.